

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE United States Patent and Trademark Office Aduress: Colvibilissioner FOR PATENTS P.O. Box 1450 Alexandria, Virginia 22313-1450 Www.uspto.gov

APPLICATION NO.	F:	ILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO
10/036,308	10/036,308 10/26/2001		Eleftherios P. Diamandis	11757.58USU1 2749	
23552	7590	08/02/2004		EXAMINER	
MERCHAN P.O. BOX 29		OULD PC	CHERNYSHEV, OLGA N		
MINNEAPOLIS, MN 55402-0903				ART UNIT	PAPER NUMBER
				1646	

DATE MAILED: 08/02/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

/		Application No.	Applicant(s)				
Office Action Summan		10/036,308	DIAMANDIS, ELEFTHERIOS P.				
	Office Action Summary	Examiner	Art Unit				
		Olga N. Chernyshev	1646				
Period fo	The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply						
A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION. - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely. - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication. - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).							
Status							
1)⊠	Responsive to communication(s) filed on 24 Ju	<u>ne 2004</u> .					
2a) <u></u> □	This action is FINAL . 2b)⊠ This action is non-final.						
3) 🗌	Since this application is in condition for allowance except for formal matters, prosecution as to the merits is						
	closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213.						
Disposition of Claims							
4) 🖾	4)⊠ Claim(s) <u>4-6 and 9-13</u> is/are pending in the application.						
	4a) Of the above claim(s) is/are withdrawn from consideration.						
5) 🗌	5) Claim(s) is/are allowed.						
6)⊠	☑ Claim(s) <u>4-6, 9-13</u> is/are rejected.						
7)	Claim(s) is/are objected to.						
8)□	Claim(s) are subject to restriction and/or	election requirement.					
Application Papers							
9)☐ The specification is objected to by the Examiner.							
10) The drawing(s) filed on is/are: a) accepted or b) objected to by the Examiner.							
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).							
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).							
11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.							
Priority u	nder 35 U.S.C. § 119						
 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some * c) None of: 1. Certified copies of the priority documents have been received. 2. Certified copies of the priority documents have been received in Application No. 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). * See the attached detailed Office action for a list of the certified copies not received. 							
Attachment	(s)						
	e of References Cited (PTO-892)	4) Interview Summary (I	PTO-413)				
3) 🔲 Inforn	e of Draftsperson's Patent Drawing Review (PTO-948) nation Disclosure Statement(s) (PTO-1449 or PTO/SB/08) No(s)/Mail Date	Paper No(s)/Mail Date 5) Notice of Informal Pare 6) Other:					

DETAILED ACTION

Response to Amendment

- 1. Claims 5 and 6 have been amended as requested in the amendment filed on June 24, 2004. Claims 4-6 and 9-13 are pending in the instant application.
- 2. Upon reconsideration, the finality of the rejection of the last Office action is withdrawn. New grounds of rejections are as follows.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

- 3. Claims 4-6 and 9-13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
- 4. Claim 4 is vague and indefinite for recitation in section (b) "detecting the amount of human kallikrein 6". Applicant is advised that term "to detect" defines discovery of the presence of a substance rather than a process of measurement of the amount. Suggested terms to use instead of "detecting the amount" to obviate this ground of rejection would be "determining the amount", "measuring the amount" or "quantifying the amount", for example.
- 5. Claims 5 and 6 are vague and ambiguous for recitation "detecting the hK6 by measuring the amount" for those reasons of record as applied to claim 4 in section 4 of the instant office action. Briefly, act of detecting does not directly correspond to measuring the amount, thus, making the instant recitation confusing in terms.

Application/Control Number: 10/036,308

Page 3

Art Unit: 1646

6. Claims 5-6 are further indefinite for reciting steps (a)-(c) or (a)-(d), respectively. Claims 5-6 are dependent claims and, therefore, must include all the limitations of the claim from which they depend. Claims 5-6 depend from claim 4, which recites three steps, (a), (b) and (c). Thus, it is not obvious how steps recited in claims 5-6 relate to the steps of claim 4. Are these steps additional or replacement steps? Furthermore, in case of claim 9, which depends from claim 6, it is not clear and cannot be determined from the claim if reference to step (a) relates to the step in

7. Claims 9-13 are indefinite for being dependent from indefinite claims.

Conclusion

8. No claim is allowed.

claim 6 or in claim 4. Clarification is required.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Olga N. Chernyshev whose telephone number is (571) 272-0870. The examiner can normally be reached on 8:00 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda G. Brumback can be reached on (571) 272-0961. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Certain papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax center located in Crystal Mall 1 (CM1). The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December

Application/Control Number: 10/036,308 Page 4

Art Unit: 1646

28, 1993) (see 37 C.F.R. \ni 1.6(d)0. NOTE: If Applicant *does* submit a paper by fax, the original signed copy should be retained by Applicant or Applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers.

Official papers filed by fax should be directed to (703) 872-9306. If this number is out of service, please call the Group receptionist for an alternative number. Faxed draft or informal communications with the examiner should be directed to (571) 273-0870. Official papers should NOT be faxed to (571) 273-0870.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Olga N. Chernyshev, Ph.D.

OLGA N. CHERNYSHEV, PH.D. PATENT EXAMINER